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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,925	04/15/2004	Kenneth T. Heruth	1023-350US01	1024

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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3735	

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10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10-826-925			

EXAMINER	
ART UNIT	PAPER
	20071002

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The Office Action mailed 7/3/07 is to be vacated.

Patricia Mallari
Patent Examiner
Art Unit 3735

Office Action Summary	Application No.	Applicant(s)	
	10/826,925	HERUTH ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-99* is/are pending in the application.

4a) Of the above claim(s) *1-23,44,57-82 and 99* is/are withdrawn from consideration.

5)☒ Claim(s) *48-50* is/are allowed.

6)☒ Claim(s) *24-38,43-49,54,56,83-87 and 89-98* is/are rejected.

7)☒ Claim(s) *39-42,55 and 88* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/30/07,1/2/07,9/26/06,8/1/06,6/16/06,3/21/06,9/29/05,9/26/05,4/7/05.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of inventions II and IIa in the reply filed on 4/16/07 is acknowledged. Claims 1-23, and 57-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to the nonelected inventions, there being no allowable generic or linking claim.

Applicant's election with traverse of A, A1, B1, C1, D3, E1, and F1 in the reply filed on 4/16/07 is acknowledged. The traversal is on the ground(s) that the application discloses that the various species are usable together and, therefore, not mutually exclusive species. This argument is found persuasive for the election requirements between species A and B, A1 and A2, B1-B3, C1 and C2, D1-D3, and E1 and EE2. The election requirements between species A1 and A2, B1-B3, C1 and C2, D1-D3, and E1 and E2 are hereby withdrawn.

However, with respect to species F1 and F2, this argument is not found persuasive because the applicants have failed to show an embodiment wherein both a processor of the medical device and a processor of the programming device determine a value of the metric indicative of sleep quality. Therefore, the election requirement between species F1 and F2 is deemed proper.

Claims 44 and 99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species F2, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/16/07.

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action

Certain references appearing on the IDS's filed 9/29/05, 6/16/06, and 1/2/07 have been crossed out because they appeared on a previously filed IDS and therefore have already been considered. Specifically, the Terry, Jr., Rapoport, and Florio references appear on both the IDS filed 9/26/05 and the IDS filed 6/16/06. The Stone '513, Schallhorn, van Lummel, Park '953, Poezevera '059, McClure, and Aminian references appear on both the IDS filed 4/7/05 and the IDS filed 6/16/06. The Kipshidze, Cho '697, and Cho '839, and Barron references appear on both the IDS filed 9/29/05 and 6/16/06. The Pless and Tcheng references appear on both the IDS filed 3/12/06 and 6/16/06. The Ni reference appears on both the IDS filed 3/21/06 and the IDS filed 1/2/07. The Kadhiresan '249 reference appears on all of the IDS's filed 9/26/05, 9/29/05, and 6/16/06.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference numeral (104) in figure 5. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 83 is objected to because of the following informalities:

On line 7 of claim 83, "and asleep" should be replaced with "and when the patient is asleep". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24-26, 30, 31, 43, and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2005/0039745 to Stahmann et al. (herein referred to as Stahmann '745). Stahmann '745 teaches a medical system comprising a medical device 401 that delivers therapy to a patient and monitors at least one physiological parameter of the patient based on a signal received from at least one sensor 480, 490. A processor 410, 411, 420 determines a value of a metric that is indicative of sleep quality based on the at least one physiological parameter, identifies a current therapy parameter set, and associates the sleep quality metric with the current therapy parameter set (see entire document, especially figs. 1-4; paragraphs 66, 67, 73, 74, 77, 80, 82, 83, 86, 91, 95-98, 128-131, 134-136 of Stahmann '745). It is noted that, in order to asses and/or change the current therapy based on the sleep quality metric, as disclosed by Stahmann '745, the processor must somehow identify the current therapy and relate or associate the current therapy with the sleep quality metric.

Regarding claim 25, the medical device monitors at least one of activity level, posture heart rate, and respiratory volume (see entire document, especially paragraph 77, 91, 101 and table 1 of Stahmann '745).

Regarding claim 26, the medical device monitors at least one of blood pressure and blood oxygen saturation (see entire document, especially paragraph 77 and table 1 of Stahmann '745).

Regarding claim 30, Stahmann '745 discloses that the processor identifies at least one of a number of arousal events and a number of apnea events during a period of sleep as the value of the sleep quality metric (see entire document, especially paragraphs 101-13 and 136 of Stahmann '745). The processor identifies when the patient is asleep prior to disordered breathing detection (see entire document, especially paragraph 46 of Stahmann '745). Also, since an arousal event is an arousal from sleep, in order to determine that an arousal event occurs, the processor must first inherently be required to determine that the patient is sleeping.

Regarding claim 31, the processor identifies when the patient is within a sleep state, and determines an amount of time that the patient was within the sleep state (See entire document, especially paragraph 47 of Stahmann '745).

Regarding claim 43, the processor comprises a processor of the medical device (see entire document, especially fig. 4 of Stahmann '745).

Regarding claim 45, the medical device comprises an implantable medical device (see entire document, especially paragraph 87 of Stahmann '745).

Claims 51, 52, 54, 56, 83, 84, 89, 93, 94, and 96-98 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2005/0085738 to Stahmann et al. (herein referred to as Stahmann '738). Stahmann '738 discloses a

medical system comprising an implantable medical device 2320 that delivers therapy to a patient, monitors at least one physiological parameter of the patient, and determines a plurality of values of a metric that is indicative of sleep quality based on the at least one physiological parameter. An external programming device 2330includes a display that receives sleep quality metric values form the implantable metric device and presents the sleep quality information to a user via the display based on the sleep quality metric values (see entire document, especially fig. 23; paragraphs 157-190 of Stahmann '738).

Regarding claims 52 and 94, the programming device presents a graphical representation of the sleep quality metric values via the display (see entire document, especially fig. 3; paragraphs 157, 159 of Stahmann '738), wherein the term "graphical", in its broadest sense, refers to a written or pictorial representation.

As to the language "the user comprises a clinician and the programming device comprises a clinician programmer" in claims 52 and 94, the applicants should note that this language is merely "intended use" language describing the intended use or user of the programming device. Such language cannot be relied upon to define over the prior art since, Stahmann '738 teaches all of the claimed structural limitations and their recited relationships. See Ex parte Masham 2 USPQ2d 1647. It is clear that the programmer of Stahmann '738 is certainly capable of being used by a clinician such that the sleep quality information may be presented to a clinician using the programmer.

Regarding claims 54 and 96, the programming device presents or displays a message (see fig. 3 of Stahmann '738) related to sleep quality based on sleep quality metric values.

As to the language "wherein the user comprises a patient and the programming device comprises a patient programmer" in claims 54 and 96, this language is also merely "intended use" language, and is treated similarly to the identified intended use language in claim 52, described above. It is further clear that the programmer of Stahmann '738 is certainly capable of being used by a patient such that the sleep quality message is presented to the patient using the programmer.

Regarding claim 56, the implantable medical device may comprise an implantable neurostimulator or an implantable drug pump (see entire document, especially paragraph 191 of Stahmann '738).

Regarding claims 83, 84, 89, 93, 94, and 96-98, Stahmann '738 discloses a medical system comprising a plurality of sensors 210, 222, each of the sensors generating a signal as a function of at least one physiological parameter of a patient and a processor 232, 236 that monitors the signals generated by the sensors (see entire document, especially fig. 2; paragraphs 61, 63, 75, 77-80, 101, 102 of Stahmann '738). The processor further identifies when the patient is attempting to sleep (see entire document, especially paragraph 170 of Stahmann '738), when the patient is asleep (see entire document, especially paragraphs 61, 171 of Stahmann '738), and a value of a metric that is indicative of sleep quality based on the identifications of when the patient is attempting to sleep and when the patient is asleep (see entire document, especially paragraphs 172-175, 182-189 of Stahmann '738).

Regarding claim 84, the processor receives an indication from the patient that the patient is attempting to sleep, wherein the processor relies on a proximity to bed sensor

to determine that the patient is attempting to sleep, and the signals from the proximity to bed sensor rely on actions by the patient, such that a signal from the proximity to bed sensor is an indication from the patient (see entire document, especially paragraph 170 of Stahmann '738).

Regarding claim 89, the processor identifies when the patient is asleep based on at least activity level (see entire document, especially paragraphs 111-125 of Stahmann '378).

Regarding claim 93, a programming device 255, 270 presents sleep quality information to a user based on the sleep quality metric values (see entire document, especially fig. 2; paragraphs 55, 56, 61, 210 of Stahmann '738).

Regarding claims 97 and 98, the system further comprises a medical device 201, wherein the processor comprises a processor of the medical device, which may be an implantable medical device (see entire document, especially figs. 2 and 23; paragraphs 67 and 158-164 of Stahmann '738).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745, as applied to claims 24-26, 30, 31, 43, and 45 above, and further in view of Stahmann '738. Stahmann '745 discloses that the sleep quality metric may comprise sleep efficiency (see entire document, especially table 1 of Stahmann '745), wherein sleep efficiency is the percentage of time in bed spent asleep (see, for example "Sleep quality and endocrine markers of sleep quality" by McArthur et al. for such a definition). Stahmann '745 further discloses that an accelerometer and a proximity to bed sensor may be included in the apparatus (see entire document, especially paragraph 91 of Stahmann '745). Stahmann '745 fails to explicitly describe how the processor determines time spent asleep and time spent in bed. However Stahmann '738 teaches that the processor determines time in bed using signals from a proximity to bed sensor to identify when the patient is attempting to sleep (see entire document, especially paragraph 170 of Stahmann '738). Further, the processor determines total time asleep using signals from an accelerometer (see entire document, especially paragraphs 117 and 171 of Stahmann '738). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention for the processor of Stahmann '745 to identify when the patient is attempting to sleep and when the patient is asleep as part of determining the time spent asleep and time spent attempting to sleep, since Stahmann '745 teaches determining sleep efficiency, which by definition, is the percentage of time in bed spent asleep and Stahmann '738 discloses that identification of when a patient is attempting to sleep and when a patient is asleep are appropriate steps in determining the time in bed and total time spent asleep, respectively.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745, as applied to claims 24-26, 30, 31, 43, and 45 above, and further in view of US Patent Application Publication No. 2005/0143617 to Auphan. Stahmann '745 teaches using sleep quality metrics, but lacks specifically reciting sleep latency. However, Auphan teaches that sleep latency (time to fall asleep) is a sleep quality metric and further shows that sleep latency is determined by identifying a first time with the patient begins attempting to sleep and a second time when the patient falls asleep (see entire document, especially paragraphs 24 and 56 of Auphan). Therefore, it would have been obvious to one of ordinary skill in the art to use sleep latency as the sleep quality metric, since Stahmann '745 teaches using a sleep quality metric, and Auphan discloses sleep latency as an appropriate such sleep quality metric.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745, as applied to claims 24-26, 30, 31, 43, and 45, above, and further in view of Auphan. Stahmann '745 teaches using sleep quality metrics, but fails to specifically recite using total sleep time. However, Auphan teaches that total sleep time is a sleep quality metric, wherein such metric is determined by identifying sleep onset (see entire document, especially paragraphs 38, 39, and 56 of Auphan). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the total sleep time as the sleep quality metric, since Stahmann '745 teaches using a

sleep quality metric, and Auphan discloses total sleep time as an appropriate such sleep quality metric.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '744, as applied to claims 24-26, 30, 31, 43, and 45, above, and further in view of US Patent Application Publication No. 2005/0065560 to Lee et al. (herein referred to as Lee' 560). Stahmann '745 teaches determining the duration of various sleep states, indicating that the most restful sleep occurs in non-REM sleep states (see entire document, especially paragraph 47 of Stahmann '745) but fails to specifically recite state 3 or 4. However, Lee '560 teaches that acquiring data about sleep states 3 or 4 would be useful for sleep quality assessment because the most restful sleep occurs in those states (see entire document, especially paragraph 73 of Lee '560). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to determine the duration of stages 3 or 4 in the system of Stahmann '745, since Stahmann '745 teaches determining the duration of non-REM sleep states as an indicator of sleep quality, and Lee '560 suggests information regarding non-REM sleep states 3 ad 4 being a good indicator of sleep quality.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745, as applied to claims 24-26, 30, 31, 43, and 45, above, and further in view of Auphan. Stahmann '745 teaches determining a plurality of sleep quality metrics (see entire document, especially paragraphs 43, 49, 67, 77; table 1 of

Stahmann '745) but is silent as to how multiple metrics are utilized. However, Auphan teaches determining a sleep quality index to indicate sleep quality, wherein the index is a value of an overall sleep quality metric based on a plurality of sleep quality metric values (see entire document, especially paragraph 58 of Auphan). Therefore, it would have been obvious to one of ordinary skill in the art to use the sleep index of Auphan in the system of Stahmann '745, since Stahmann '745 discloses using multiple metrics, and the sleep index of Auphan is a means for utilizing such multiple metrics.

Regarding claim 34, the processor applies a weighting factor to at least one of the metric values to determine the overall sleep quality metric (see entire document, especially paragraph 58 of Auphan).

Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745, as applied to claims 24-26, 30, 31, 43, and 45, and further in view of Stahmann '738. Stahmann '745 lacks a programming device to present sleep quality information to a user. However, Stahmann '738 teaches a medical system comprising an implantable medical device for delivering therapy and determining sleep quality metric values, and a programming device for presenting sleep quality information to a user base don the sleep quality metric values determined by the processor of the implantable medical device (see entire document, especially fig. 23; paragraphs 157, 159, 189, 190 of Stahmann '738). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the programming device of Stahmann '738 with the system of Stahmann '745 in order to provide the information to

a health care professional to provide adjustment to therapy and/or diagnose disorders (see entire document, especially paragraph 190 of Stahmann '738).

Regarding claim 37, the programming device comprises a programmer that presents a message related to sleep quality base don the sleep quality metric values (see entire document, especially fig. 3; paragraphs 157, 159, and 190 of Stahmann '738). As to the language "the user comprises a patient" and "to the patient" on lines 2 and 3 of claim 37, the applicant should note that the designation of a "patient" here is merely "intended use" language, which cannot be relied upon to define over the prior art, since Stahmann '745, as modified, teaches all of the claimed structural limitations and their recited relationships. See Ex parte Masham 2 USPQ2d 1647. The programming device may certainly present the information in figure 3 to anyone, such as a patient.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745 in view of Stahmann '738, as applied to claims 35 and 37 above, and further in view of US Patent No. 6,273,856 to Sun et al. Stahmann '745, as modified, teaches presenting the information in the form of a simple listing or tabular form (see fig. 3 of Stahmann '738), rather than as a trend diagram, histogram, or pie chart. However, Sun teaches that data may equally be displayed for a clinician's use as a histogram or as a simple listing or data as collected chronologically (col. 5, lines 43-51 of Sun). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a histogram in place of the listing of Stahmann '745, as modified, since

Sun shows the two formats to be functionally equivalent for presenting data to a clinician.

Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '745, as applied to claims 24-26, 30, 31, 43, and 45 above, and further in view of US Patent Application Publication 2005/0061320 to Lee et al. (herein referred to as Lee '320). Stahmann '745 teaches the medical device being an implantable medical device, such as a cardiac rhythm management device (see entire document, especially fig. 4; paragraph 88 of Stahmann '745) rather than a neurostimulator or drug pump. However, Lee '320 teaches a system which determines values of a sleep quality metric to assess and/or adjust therapy, wherein the device used for delivering therapy and monitoring at least one physiological parameter may be any of a cardiac rhythm management (CRM) device, an implantable/trial drug delivery device or implantable/trial neurostimulator (see entire document, especially paragraphs 44, 46, 54, 57, 80, 81, 101, 118, 148, 188, and 192-194 of Lee '320). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the drug pump of Lee '320 as the medical device of Stahmann '745, since Stahmann '745 teaches using a CRM device, and Lee '320 discloses that a drug pump may be used to contribute to the patient monitoring, diagnosis, and therapy functions of such a medical system in place of CRM device.

As to the term "trial" in claim 47, the neurostimulator and/or delivery device described by Lee '320 is capable of being used on a trial basis. The term trial appears

to merely be an "intended use" limitation, wherein such a limitation cannot be relied upon to define over the prior art, since Stahmann '745 in view of Lee '320 teaches all of the claimed structural limitations and their recited relationships. See Ex parte Masham 2 USPQ2d 1647.

Claims 53 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738, as applied to claims 51, 52, 54, and 56 above, and further in view of US Patent No. 6,273,856 to Sun et al. Stahmann '738 teaches presenting the information in the form of a simple listing or tabular form (see fig. 3 of Stahmann '738), rather than as a trend diagram, histogram, or pie chart. However, Sun teaches that data may equally be displayed for a clinician's use as a histogram or as a simple listing or data as collected chronologically (col. 5, lines 43-51 of Sun). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a histogram in place of the listing of Stahmann '738, since Sun shows the two formats to be functionally equivalent for presenting data to a clinician.

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738, as applied to claims 51, 52, 54, 56, 83, 84, 89, 93, 94, and 96-98 above, and further in view of US Patent Application Publication No. 2005/0043772 (Stahmann '772). Stahmann '738 discloses determining time in bed (which is the same as time attempting to sleep) by a combination of posture sensing and sensing the proximity of the patient to the bed (see entire document, especially paragraph 169 of

Stahmann '738). Stahmann '738 is silent as to how the posture sensor and proximity to bed sensor are used to determined time in bed. However, Stahmann '772 discloses determining the patient is lying down in bed by using the posture sensor and bed proximity sensor (see entire document, especially paragraph 84 of Stahmann '772). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the posture sensor and proximity to bed sensor to determine when the patient is lying down in bed, as shown by Stahmann '772, in the system of Stahmann '738, since Stahmann '738 discloses determining when the patient is in bed using a posture sensor and a proximity to bed sensor, and Stahmann '772 disclose an appropriate method for doing so.

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738 in view of Stahmann '772, as applied to claim 85 above, and further in view of US Patent No. 5,593,431 to Sheldon. Stahmann '738, as modified teaches using a multiaxis accelerometer as the posture sensor, but lacks a plurality of orthogonally aligned accelerometers. However, Sheldon discloses a posture sensor comprising a plurality of orthogonally aligned accelerometers, wherein the processor identifies when the patient is lying down based on a DC component of each of the signals (see entire document, especially the abstract; col. 5, lines 42-64; col. 16, lines 15-26 and lines 45-61 of Sheldon). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the posture sensor of Sheldon in place of that of Stahmann '738, as it would merely be the substitution of one known

posture sensor for another, to yield the predictable result of a system having a posture sensor.

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738, as applied to claims 521, 52, 54, 56, 83, 89, 93, 94, and 96-98 above, and further in view of US Patent Application Publication No. 2004/0215269 to Burnes et al. Stahmann '738 lacks identifying when the patient is attempting to sleep based on an activity level of the patient. However, Burnes discloses a system where the processor monitors at least one signal that varies as a function of activity of the patient and identifies when the patient is attempting to sleep based on a level of activity of the patient (see entire document, especially paragraphs 29, 39 of Burnes), wherein Burnes discloses a determination of inactive state as an indication that the patient is attempting to sleep. Therefore, it would have been obvious to one of ordinary skill in the art replace the means for identifying when the patient is attempting to sleep of Stahmann '738 with that of Burnes, as it would merely be the substitution of one known means for identifying when the patient is attempting to sleep for another, to yield the predictable result of a system having a means for identifying when the patient is attempting to sleep.

Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738, as applied to claims 521, 52, 54, 56, 83, 89, 93, 94, and 96-98 above, and further in view of US Patent Application Publication No. 2001/0031930 to Roizen et

al. Stahmann '738 lacks identifying when the patient asleep based on any of blood pressure, blood oxygen saturation, partial pressure of oxygen in blood, partial pressure of oxygen in cerebrospinal fluid, muscular activity, arterial blood flow, and galvanic skin response. However, Roizen discloses using muscular activity (EMG) to identify sleep onset (see entire document, especially paragraphs 15, 18, 25 of Roizen). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to replace the means for identifying when the patient is asleep of Stahmann '738 with that of Roizen, as it would merely be the substitution of one means for identifying when the patient is asleep for another, to yield the predictable result of a system having a means for identifying when the patient is asleep.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738, as applied to claims 51, 52, 54, 56, 83, 84, 89, 93, 94, and 96-98 above, and further in view of Stahmann '745. Stahmann '738 teaches determining undisturbed respiration sleep efficiency or undisturbed sleep efficiency as the sleep quality metric, but lacks determining sleep efficiency. However, Stahmann '745 teaches determining sleep efficiency as a sleep quality metric, wherein sleep efficiency is defined as the percentage of time in bed spent asleep (see "Sleep quality and endocrine markers of sleep quality" by MacArthur et al. for such definition), wherein the time in bed is equivalent to the time attempting to sleep (see entire document, especially table 1 of Stahmann '745) . Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to determine sleep efficiency as one of the sleep quality

metrics of Stahmann '738, since Stahmann '738 discloses calculating at least one sleep quality metric, and Stahmann '745 describes sleep efficiency as an appropriate such metric.

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann '738, as applied to claims 51, 52, 54, 56, 83, 84, 89, 93, 94, and 96-98 above, and further in view of US Patent Application Publication No. 2005/0143617 to Auphan. Stahmann '738 teaches using sleep quality metrics, but lacks specifically reciting sleep latency. However, Auphan teaches that sleep latency (time to fall asleep) is a sleep quality metric and further shows that sleep latency is determined by identifying a first time with the patient begins attempting to sleep and a second time when the patient falls asleep (see entire document, especially paragraphs 24 and 56 of Auphan). Therefore, it would have been obvious to one of ordinary skill in the art to use sleep latency as the sleep quality metric, since Stahmann '738 teaches using a sleep quality metric, and Auphan discloses sleep latency as an appropriate such sleep quality metric.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 24 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 11/081811 to Heruth (herein referred to as application '811). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 of application '857 claims a medical device having all of the limitations of the medical

device of claim 24 of the instant application, wherein the medical device comprises the monitor, such that the medical device delivers therapy and monitors the physiological parameter.

Claims 24, 38, and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending application '811 in view of Stahmann '745. Claim 3 of application '811 teaches all of the limitations of claim 24 of the instant application except that in claim 3 of application '811, a medical device and a monitor are provided separately for delivering therapy and monitoring the physiological parameter, respectively. However, Stahmann '745 shows a medical device that both delivers therapy and monitors a physiological parameter (see entire document, especially fig. 4, paragraphs 87-89, 91 of Stahmann '745). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the medical device of Stahmann '745 in place of the separate medical device and monitor of claim 3 of application '811, as it would merely be the substitution of one known means for therapy and monitoring for another.

Regarding claims 38 and 43, claims 8 and 10, respectively of application '811, as modified by Stahmann '745 (described above), discloses all of the claimed limitations of claims 38 and 43, respectively, of the instant application.

Claims 35-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of application '811, as modified by Stahmann '745 above, and further in view of Stahmann '738. Claim 5, as modified, teaches all of the claimed limitations of claim 35 of the instant

application except that in claim 5, as modified, a computing device present sleep quality information instead of the programmer recited in claim 35 of the instant application. However, Stahmann '738 teaches a medical system wherein a programmer is used to present sleep quality information to a user (see entire document, especially paragraphs 157 and 159 of Stahmann '738). Therefore, it would have been obvious to one of ordinary skill in the art to use a programmer as the computing device of claim 5, as modified, since claim 5, as modified, discloses using a computing device, an Stahmann '736 teaches a programmer as an appropriate such computing device for presenting sleep quality information.

Regarding claims 36 and 37, claims 6 and 7 of application '811, as modified by Stahmann '745 and Stahmann '738 teach all of the claimed limitations of claims 36 and 37 of the instant application.

Claim 24 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 11/081,857 (herein referred to as application '857). Claim 4 of application '857, recites all of the claimed limitations of claim 24 of the instant application except that claim 4 of application '857 does not explicitly recite a step of identifying a current therapy parameter set. However, in order to associate any information with the current therapy parameter set, the set must first be identified. Therefore, the step of identifying the parameter set is inherent.

Claim 51 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of copending Application No.

11/081857 to Heruth et al. (herein referred to as application '857). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 14 of application '857 claims a medical device having all of the limitations of the medical device of claim 51 of the instant application.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented

Allowable Subject Matter

Claim 38 would be allowable if the double patenting rejection were overcome and the claim were rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 39-42, 55, and 88 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 48-50 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 38-42 and 55, the primary reason for allowance is the inclusion of the processor determining a representative value of the sleep quality metric for each of a plurality of therapy parameter sets, in combination with all of the other limitations of the claims, which is not found in the prior art.

Regarding claims 48-50, the primary reason for allowance is the inclusion of the means for associating the sleep quality metric value with the current therapy parameter set, in combination with all of the other limitations of the claims, which is not found in the prior art. This means plus function language fulfills the 3-prong test set forth in MPEP § 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. The means set forth in the specification is a processor that stores the sleep quality metric value in a memory such that it is associated in the memory with the current therapy parameter set. The prior art fails to teach a medical system, as claimed, comprising such a means for associating the sleep quality metric value with the current therapy parameter set.

Regarding claim 88, the primary reason for allowance is the inclusion of the processor monitoring a signal that varies as a function of a level of melatonin within a bodily fluid of the patient and identifying when the patient is attempting to sleep based on the melatonin level, in combination with all of the other limitations of the claims, which is not found in the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Mallari
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Art Unit 3735